Relationship between Dermatologists, Health Maintenance Organizations, and Clinical Laboratories

By the Staff of
The Florida House of Representatives
Committee on Health Care Licensing & Regulation
The Honorable Mike Fasano, Chair

December, 1999

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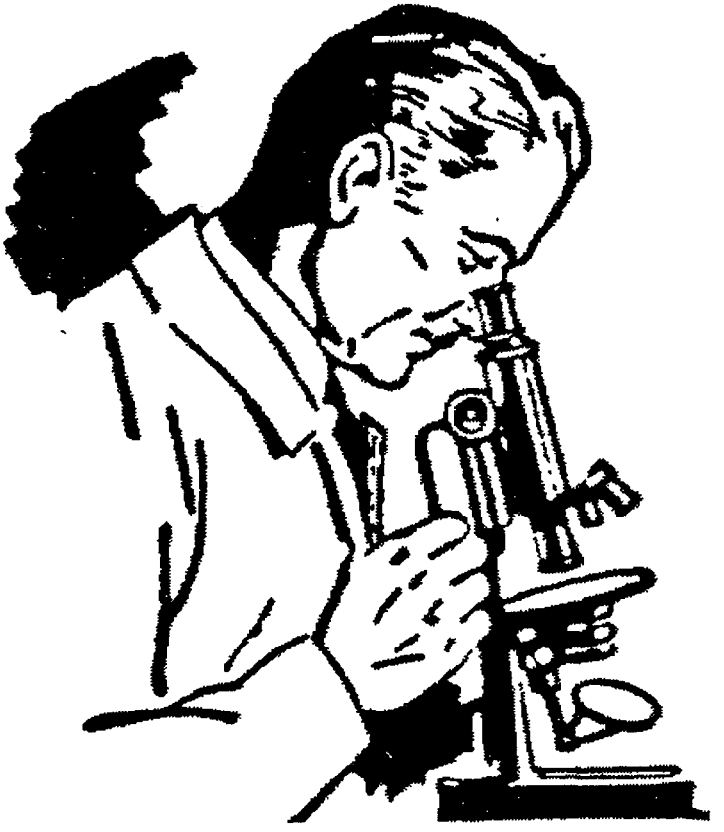

The Florida House of Representatives
Committee on Health Care Licensing & Regulation
The Honorable Mike Fasano, Chair
The Honorable Everett Kelly, Vice Chair

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INTRODUCTION

Following the 1999 Session, Chairman Fasano received input from a number of dermatologists and other individuals who expressed concerns about the accuracy and timeliness of tissue analyses (anatomical pathology) received from various clinical laboratories as well as the requirement that the health care provider must use specific laboratories as a condition of their managed care contract. These health care providers stated that as a condition of their contract, they are required to use specific clinical laboratories whose pathology reports in some instances, are not "of the quality and appropriateness that are required to practice high level care."

It was suggested that the Committee on Health Care Licensing & Regulation conduct a review to determine whether the Legislature should modify the law as it relates to selection of laboratories to review tissue samples. This request was forwarded to the Speaker of the House for consideration as an interim project. On June 4, 1999, the Speaker released the approved list of 1999 interim projects, and the committee was authorized to proceed with this review.

The following report is a compilation of information gathered from individuals within the dermatology profession, selected health maintenance organizations within the managed care industry, agency personnel, and other public and private sources with expertise in specific areas. It is intended to provide options that the Legislature might consider in determining whether to change existing law as it relates to the process by which clinical laboratories are selected to perform tissue analyses or the reporting of complaints to the Agency for Health Care Administration.

EXECUTIVE SUMMARY

Chapter 483, Part I, Florida Statutes, was passed in 1967 to require the licensure of facilities performing clinical laboratory testing for the purpose of the diagnosis and treatment of medical conditions.

The regulatory authority for clinical laboratory licensure was granted to the Department of Health and Rehabilitative Services (HRS). This authority was transferred to the Agency for Health Care Administration when it was created in 1992.

Laboratories are licensed according to their testing specialties, including chemistry, microbiology, hematology, pathology, etc. Chapter 59A-7, Florida Administrative Code (F.A.C.), contains specific technical requirements for the various specialties, as well as general laboratory requirements with which all licensed laboratories must comply as a condition of licensure. Biennial licensure surveys (inspections) are conducted on all licensed laboratories, except those performing the simplest of laboratory tests.

As of October 1999, the Agency had 10,506 active clinical laboratory licenses. Of these facilities, 497 were licensed in the specialty of pathology.

Staff has reviewed statutory requirements relating to health maintenance organizations (HMOs), health care providers and clinical laboratories, as well as received input from appropriate health care providers, managed care groups, agency personnel, and clinical laboratories through questionnaires, surveys and personal reviews.

A questionnaire/survey was mailed to approximately 450 Dermatologists and Dermatologic Surgeons, and the 35 health maintenance organizations (HMOs) listed as operating in Florida during calendar 1998. Also, staff requested input from the three clinical laboratories that review the majority of tissue samples in Florida. The committee received responses from approximately 58% of the dermatologists, 30% of the HMOs, and no responses from the three clinical laboratories.

The following is a summary of the findings, conclusions, and recommendations contained in this report.

Conclusions

Based on the findings in this report, the following conclusions are provided:

1. Quality of care or the quality of the opinion issued for the samples analyzed was the most important single issue identified by the dermatologists. They identified accuracy of the opinion issued by a clinical laboratory as being of critical importance.

The accuracy of the opinion issued by a clinical laboratory can be a life or death matter as documented by public testimony at the committee's hearing on November 3, 1999. Also, the Boston Globe article dated December 1, 1999, cited research which documented the need for a second opinion in many instances to ensure the accuracy of the first opinion. This John Hopkins Medical Institutions study found 1.4% of biopsy analyses resulted in an inaccurate diagnosis. Therefore, the accuracy of the analysis must be ensured and potential health hazards must be detected at the earliest point in time.

2. The second issue of primary importance to the dermatologists was the ability to either select the clinical laboratory, or as an alternative, to be able to select the clinical laboratory to issue a second opinion when there was documented concern as to the quality of the first opinion.

3. The dermatologists also identified that the turnaround time on tissue samples from laboratories was an important concern. It appears that the turnaround time on tissue samples sent to clinical laboratories of their choice was considerably faster than from the clinical laboratories managed care required them to use. However, it should be pointed out that a number of HMOs responded that if the dermatologists requested a faster turnaround time, the clinical laboratory they were required to use would comply.

4. Of the responding dermatologists, 69% reported incorrect diagnosis accuracy and 58% reported lost tissue samples. However, only 2% reported filing a complaint with the Agency for Health Care Administration, the agency that issues licenses to the clinical laboratories.

   Of the HMOs responding to the committee, 100% stated that they had no knowledge of lost or incorrect diagnoses. However, in their response to a questionnaire sent to all HMOs by the Agency for Health Care Administration, United Healthcare of Florida, Inc., stated that they had knowledge of complaints filed relative to misdiagnoses of tissue samples. In addition, one HMO that responded to the agency, but not to the committee, stated that they had knowledge of complaints filed relative to misdiagnoses of tissue samples (Prudential Health Care Plan).

   Humana reported to the agency that the issue was pending review; however, Humana did not respond to repeated requests for clarification. The agency was eventually informed by Humana that they did not maintain their records so as to obtain the requested information relating to incorrect diagnoses. Other HMOs nevertheless were able to provide the requested information to the agency. While there may not have been an attempt to misinform the committee, it would appear that the responses to the agency and the committee were not compared and may have been prepared by different individuals.

A review of the statutes relating to clinical laboratories does not provide for a specific process or procedure for filing complaints about the quality of analyses the same as is provided in ch. 455, Florida Statutes, for physicians and other medical professionals.

5. Of the responding dermatologists, 98% would prefer that tissue samples be analyzed by a dermatopathologist rather than a general pathologist. However, a number of dermatologists responded that they know pathologists who are as knowledgeable and qualified as a dermatopathologist and issued opinions that were of equal quality.

   The knowledge and qualifications of the pathologist that issues the opinion was the primary reason given by the dermatologists for wanting to select which clinical laboratory should analyze tissue samples.

6. Due to the need for accurate diagnoses in life and death cases and the complexity of the diagnostic analysis, it would appear reasonable that such samples be handled differently from other clinical laboratory samples.

Recommendations

There are three options that are available to address the need to ensure the diagnostic accuracy and quality of clinical laboratories selected:

A. Change the law to require HMOs to select a group of several clinical laboratories from which dermatologists can then select their preferred provider of laboratory services;

B. Change the law to allow dermatologists to select the clinical laboratories to be used based on qualifications and their professional judgment; or

C. Continue to allow HMOs to select the clinical laboratory(s) for a dermatologist to use, but authorize the dermatologist to obtain second opinions from a laboratory of their choice when they provide documentation to the HMO to justify the need for a second opinion.

Based on the findings and conclusions in this report, the following recommendations are provided:

1. Allow the HMOs to continue to provide a group of authorized clinical laboratories from which a dermatologist may choose; however, grant the dermatologist the authority to obtain a second opinion from a laboratory of their choice when they provide documentation to the HMO which justifies the need for a second opinion.

2. A specific procedure should be provided either by rule of the agency or by statute to address complaints against clinical laboratories. Such procedure should:

   (a) require the dermatologist or other physicians to notify the HMO of all questionable analyses or lost samples; and

   (b) require the HMO to maintain a record of all complaints and report such complaints to the Agency for Health Care Administration.

METHODOLOGY

Chairman Fasano held a meeting in June 1999, with all interested parties and staff to discuss this project. Subsequently, staff has reviewed statutory requirements relating to managed care (HMOs), health care providers and clinical laboratories; met with personnel of the Agency for Health Care Administration, Department of Insurance, various professional associations, health care providers and managed care groups to discuss the project; obtained lists of membership/licensees; and developed potential questions for a questionnaire or survey.

In August 1999, a questionnaire/survey was developed by staff and mailed to approximately 450 Dermatologists and Dermatologic Surgeons, and the 35 health maintenance organizations (HMOs) listed as operating in Florida during calendar 1998. Also, staff requested input from the three clinical laboratories that review the majority of tissue samples in Florida. The committee received responses from approximately 58% of the dermatologists, 30% of the HMOs, and no responses from the three clinical laboratories.

BACKGROUND INFORMATION

Legislative History

- *Clinical Laboratories*

Chapter 483, Part I, Florida Statutes, was passed in 1967 to require the licensure of facilities performing clinical laboratory testing for the purpose of the diagnosis and treatment of medical conditions. Exemptions to the statute included facilities owned and operated by the federal government, research laboratories and physician office laboratories comprised of 5 or less physicians performing testing only on their own patients. Licensed facilities were primarily comprised of independent (free standing) laboratories, hospital laboratories, blood banks, and plasmapheresis centers. As of October 1999, the Agency had 10,506 active clinical laboratory licenses. Of these facilities, 497 were licensed in the specialty of pathology.

The regulatory authority for clinical laboratory licensure was granted to the Department of Health and Rehabilitative Services (HRS). This authority was transferred to the Agency for Health Care Administration when it was created in 1992.

In 1992-93, the federal government implemented the Clinical Laboratory Improvement Amendments (CLIA). This legislation encompasses all laboratories testing regardless of the location at which the testing is performed. As a result of these federal requirements, Chapter 483, Part I, Florida Statutes, was amended to require licensure of all testing locations.

As a result of these changes, physician office laboratories (regardless of the number of physicians in the group) were also required to obtain licensure under Chapter 483, Part I, Florida Statutes. Exemptions to both state licensure and federal CLIA certification are still extended to facilities performing research and federally owned and operated facilities.

Laboratories are licensed according to their testing specialties, including chemistry, microbiology, hematology, pathology, etc. Chapter 59A-7, Florida Administrative Code (F.A.C.), contains specific technical requirements for the various specialties, as well as general laboratory requirements with which all licensed laboratories must comply as a condition of licensure. Biennial licensure surveys (inspections) are conducted on all licensed laboratories, except those performing the simplest of laboratory tests.

Section 483.041, Florida Statutes, defines a clinical laboratory as the physical location where one of the following services are performed: clinical laboratory services - examination of fluids or other materials taken from the human body; anatomic laboratory services - examination of skin and tissue taken from the human body; and cytology laboratory services - examination of cells from individual tissues or fluid taken from the human body. A clinical laboratory examination is defined as a procedure performed to deliver the listed service(s), including the interpretation of

such service(s). A pathologist is responsible for analysis and interpretation of the various services performed in a clinical laboratory.

- *Dermatology/Pathology*

Medical doctors in Florida have been licensed by the State since 1889. Medical doctors were originally licensed and regulated by the Board of Medical Examiners. In 1969, the Department of Occupations and Professions was created and all of the various medical professions and most of the nonmedical groups were placed under the new department. In 1979, the department was reorganized and renamed the Department of Professional Regulation. In 1986, the Board of Medical Examiners was renamed the Board of Medicine. In 1993, the Legislature abolished the Department of Business Regulation and the Department of Professional Regulation and merged their functions into the newly-created Department of Business and Professional Regulation. In 1994, regulation of all medical professions was transferred from the Department of Business and Professional Regulation to the Agency for Health Care Administration. In 1996, regulation of the medical professions was transferred to the Department of Health, effective July 1, 1997. At the present time, the Department of Health contracts with the Agency for Health Care Administration to carry out the complaint, investigation and prosecution functions for the various medical professions.

Dermatology is defined as the medical study of skin physiology and pathology. Dermatologists in Florida are licensed as medical physicians and regulated by the Board of Medicine within the Department of Health, pursuant to ch. 458, Florida Statutes.

Pathology is defined as the branch of medicine concerned with the study of the nature of disease, its causes, processes, development, and consequences. A pathologist is responsible for analysis and interpretation of the various services performed in a clinical laboratory. A dermatopathologist is a specialty within pathology that specializes in skin/tissue related problems, and in many instances, is responsible for analysis and interpretation of skin/tissue related services performed in a clinical laboratory. A pathologist is licensed pursuant to ch. 458, Florida Statues, and regulated by the Board of Medicine of the Department of Health.

The board does not license physicians by the various specialties, such as dermatology or pathology. These specialty designations are obtained by a medical physician meeting the requirements of the various national boards representing such specialties. When the Department of Health has its physician profiling system fully implemented, information by specialties will be available.

The professional associations for these two professions estimate that there are approximately 700-800 dermatologists and 700-800 pathologists licensed in the State of Florida by the Board of Medicine. An estimate of the number of dermatopathologists was not available.

- *Health Maintenance Organizations*

Health maintenance organizations (HMOs) have been operating in Florida since 1973 and were originally authorized as a means of controlling excessive increases in annual health care costs and are regulated by the Department of Insurance as to their finances pursuant to ch. 641, Florida Statutes.

In 1987, HMOs were initially certified and regulated as to the quality of care by the Department of Health and Rehabilitative Services (HRS) pursuant to ch. 641, Florida Statutes. On January 28, 1988, HRS promulgated a rule that provided for medical records systems and quality of care standards. HRS also conducted quality reviews and investigated quality of care complaints.

In 1992, when the Agency for Health Care Administration was created by ch. 92-33, Laws of Florida, certification and regulation of HMOs was transferred to the Agency for Health Care Administration. However, the financial regulation and fiscal stability requirements for HMOs remained the responsibility of the Department of Insurance. In 1998, the Managed Care Ombudsman Committee was established with the responsibility of reviewing disputes and attempting to resolve such disputes to the satisfaction of the HMO and patient or HMO member.

The rapid growth of HMOs has changed the financing and delivery of health care in Florida and throughout the U.S. While other forms of managed care, such as preferred provider organizations (PPOs), also flourish, HMOs usually control the health care they provide and its costs most closely. Therefore, they have received tremendous attention from the public, the media and from elected officials.

Two major types of HMOs are the group model and the staff model. The group model HMOs involve an exclusive or near-exclusive two-way commitment between the HMO and a group of physicians. They are more centralized and work with a physician's group that operates out of one or a few facilities. Staff model HMOs are similar to group HMOs except that they may have staff employed by the HMO rather than contract with a group of physicians.

HMO enrollment can be divided into three major categories: commercial; Medicaid; and Medicare. Commercial enrollment accounts for the majority of HMO members. In 1995, membership was: commercial - 75%; Medicaid - 11%; and Medicare - 14%. As of March 31, 1999, membership was: commercial - 75%; Medicaid - 9%; and Medicare - 16%.

There has been tremendous growth in HMO membership in Florida since 1985. In 1985, Florida's share of the market was only 6% with the U.S. share at 8%. In 1997, Florida's share of the market had grown to 29% while the U.S. share was only 27%. In 1985, Florida had a total of 27 HMOs with an estimated enrollment of 769,000. In 1997, total membership had increased to 4.5 million, placing Florida third among states in total membership, behind California and New York. As of March 31, 1999, total HMO membership in Florida was 4.9 million persons.

Sometimes two or more HMOs have the same corporate ownership. This can happen through mergers, takeovers, or because a firm uses different plans to serve different markets. As of November 1999, after consolidating by ownership, there were 30 organizations licensed in Florida.

FINDINGS

Industry Positions

The points presented in the ensuing two sections are the positions of the dermatologists and the managed care industry (HMOs). The positions reported are those furnished to staff in response to a survey or questionnaire relating to this project.

- **Dermatologists** - Based on testimony from the President of the Florida Society of Dermatology, and the 259 responses received to the questionnaire, it can be concluded that the dermatologists would prefer selecting the clinical laboratory that does the analysis of patient tissue samples. They are of the opinion that managed care is currently selecting the approved clinical laboratories based on the lowest price, rather than the quality and timeliness of their work.

- **Health Maintenance Organizations** - Of the 30 HMOs, 9 responded to the questionnaire. Based on this information, it was evident that the HMOs want to continue to select the authorized clinical laboratories that dermatologists who participate in an HMO plan must use. The HMOs are of the opinion that if a clinical laboratory meets the state licensing requirements, it is assumed that they perform acceptable work. Price is an important factor for their consideration because of the need to contain or reduce overall costs.

  A review of the income and expense statement for all HMOs provided by the Department of Insurance, disclosed that for all of fiscal 1998, the industry lost $27.6 million. For the three-month period through June 30, 1999, the industry reported a lost of $36.2 million. In 1998, there were 35 HMOs operating in Florida; however, through consolidation, purchase, or closing their operations in Florida, there were only 30 commercial HMOs as of November, 1999.

- **Clinical Laboratories** - While there are approximately 500 clinical laboratories that analyze tissue samples (anatomical pathology) in Florida, most of the tissue samples are analyzed by either one or some combination of the following three clinical laboratories: SmithKline Beecham Clinical Laboratories; Laboratory Corporation of America; or Quest Diagnostics Laboratories. As of the date of this report, the committee had not received any comments from these three laboratories as to whether or not they have a position on this issue.

Questionnaire/Survey Findings

Staff developed and mailed a questionnaire/survey to approximately 450 Dermatologists and Dermatologic Surgeons, and all 30 health maintenance organizations (HMOs) operating in Florida. Also, staff requested input from the three clinical laboratories that review the majority of tissue samples in Florida. A copy of the questionnaire and a summary of the results are included in the Appendix. The clinical laboratories had not responded as of the date of the report. The following is a summary of responses to selected questions on the questionnaires sent to the dermatologists and HMOs:

Dermatologists

1. Of the 444 questionnaires mailed to Florida licensed dermatologists and dermatologic surgeons, the committee received a response from 259 or 58%. A response rate of 58% is considered acceptable for drawing statistically valid conclusions. However, it should be pointed out that all 259 respondents did not answer every question.

2. Of the 253 dermatologists that responded to the question, 215 or 85% stated they currently participated in manage care to some degree. Of those dermatologists responding to the follow-up question, 65% stated they would expand their participation in managed care if no restrictions were placed on their choice of laboratories to use for analyzing samples.

3. When asked whether or not they were required to use a specific clinical lab or group of labs by their managed care contract, 95% of the respondents stated they were.

4. Nearly 58% of the dermatologists that responded to the questionnaire identified one or more examples of lost samples and 69% identified examples of one or more incorrect diagnoses. However, only 2% reported filing a complaint with the Agency for Health Care Administration, the agency that issues licenses to the clinical laboratories.

5. A majority of the dermatologists who responded identified that the turnaround time on tissue samples from laboratories of their choice was considerably faster than from the laboratories managed care required them to use.

   For instance, 63% received responses in three days or less, while an additional 10% (total of 73%) received responses in four days or less from laboratories of their choice.

6. The response time from laboratories managed care required them to use was considerably longer. The results fell into three basic groups: 15% responded that it took 7 days; 28% responded that it took 10 days; and the largest single group, 32% stated it took 14 days. In summary, 60% responded that it took between 10 and 14 days to receive a response from the laboratories that managed care required them to use.

7. There are approximately 500 clinical laboratories licensed by the Agency for Health Care Administration that perform anatomical pathology.

   However, based on the responses received from dermatologists, **the great majority of dermatologists were required to use either one or some combination of the following three laboratories for their skin and tissue samples: SmithKline Beecham Clinical Laboratories; Laboratory Corporation of America; or Quest Diagnostics Laboratories.**

   SmithKline was listed on 145 responses, Laboratory Corporation of America was listed on 119 responses, and Quest was listed on 45 responses. The closest other laboratory named in the responses, was only listed as being used by 18 dermatology offices. However, many of the 259 respondents did not list the laboratory(s) they were required to use. Also, it should be pointed out that SmithKline Beecham Clinical Laboratories was recently acquired by Quest Diagnostics Laboratories.

8. When asked if they obtained a second opinion if the laboratory results were questionable, 76% stated they did. However, if required to use a specific laboratory by managed care, 161 or 90% of the respondents stated they were not allowed by managed care to obtain a second opinion. Approximately 10% stated that managed care allowed them to obtain a second opinion with prior approval.

9. Of those responding, 95% stated they had never been involved in a lawsuit as a result of inaccurate diagnoses. Only 5% stated they had been party to a lawsuit.

10. Of the responding dermatologists, 98% would prefer that tissue samples be analyzed by a dermatopathologist rather than a general pathologist.

11. Of those responding, 98% reported that the dermatologist should be allowed to select the most qualified laboratory based on their professional judgment.

    As an alternative to the dermatologist selecting the laboratory, 82% responded that the ability to get second opinions from the laboratory of their choice would be an acceptable alternative.

Health Maintenance Organizations

1. Of the questionnaires mailed to the 30 Florida licensed health maintenance organizations (HMOs), the committee received a response from 9 or 30%. A list of the HMOs that did not respond is included in the Appendix. In addition, a request was made of the representatives of the three largest clinical laboratories in Florida for any input that the clinical laboratories would like to provide to the committee for consideration. As of the date of the report, no responses had been received.

2. In 1998, there were 35 HMOs operating in Florida; however, through consolidation, purchase, or closing their operations in Florida, there were only 30 HMOs as of November, 1999. A review of the financial reports submitted to the Department of Insurance by all Florida-licensed HMOs reflected that for the period ending June 30, 1999, 24 of the 35 HMOs reported net operating losses and only 11 reported a profit for the period. In summary, the combined reports for all 35 HMOs licensed in Florida reported a net operating loss of $36.2 million for the 3 month period through June 30, 1999. For all of 1998, these same 35 HMOs reported a net operating loss of $27.6 million.

3. While only 3 of the 9 HMOs responding answered the question, based on their response, tissue samples (anatomical pathology) amount to approximately 2-5% of all samples tested by the clinical laboratories.

4. Of the 9 responding HMOs, 78% verified that dermatologists with which they contracted were required to use either one or some combination of the following three laboratories for their skin and tissue samples: SmithKline Beecham Clinical Laboratories; Laboratory Corporation of America; or Quest Diagnostics Laboratories.

5. Of the 9 responding HMOs, 100% stated that they had no knowledge of lost or incorrect diagnoses. However, in their response to a questionnaire sent to all HMOs by the Agency for Health Care Administration, United Healthcare of Florida, Inc., stated that they had knowledge of complaints filed relative to misdiagnoses of tissue samples. In addition, one HMO that responded to the agency, but not to the committee, stated that they had knowledge of complaints filed relative to misdiagnoses of tissue samples (Prudential Health Care Plan).

   Humana reported to the agency that the issue was pending review; however, Humana did not respond to repeated requests for clarification. The agency was eventually informed by Humana that they did not maintain their records so as to obtain the requested information relating to incorrect diagnoses. Other HMOs nevertheless were able to provide the requested information to the agency.

6. When the HMOs were asked if they would consider removing anatomical pathology in its entirety from capitated clinical laboratory contracts, 28% responded yes, and 78% responded no.

   As an alternative, the HMOs were asked to consider allowing a dermatologist to select the clinical laboratory if the dermatologist documented that the contracted clinical laboratory did not meet the standards required to perform quality analyses of tissue samples, 33% responded yes, and 67% responded no.

7. While 37% of the HMOs responded that 10-14 days was an acceptable turnaround time for tissue samples, 63% responded that it was unacceptable. In addition, several HMOs identified an average turnaround time that was considerably faster than 10-14 days.

Johns Hopkins Medical Institutions Study

The following findings were taken from a Boston Globe article by Karen Hsu, Globe Correspondent, dated December 1, 1999. The title of the article was "Biopsies need 2nd review, researchers say."

1. In a recently released study of 6,171 cancer patients referred to Johns Hopkins Medical Institutions in Baltimore, Maryland, researchers found 86 patients, or 1.4%, who initially had a "totally wrong" diagnosis after a biopsy result.

2. Patients have long been told to seek a second opinion from an examining doctor, but they also should ask for a second review on laboratory readings by pathologists to prevent the wrong treatment, researchers say.

3. Between January 1995 and December 1997, two pathologists at Sturdy Memorial Hospital in Attleboro, Massachusetts, allegedly misread 20 biopsies on 19 patients. The hospital now has biopsies reviewed by two pathologists, instead of one.

4. The medical director of head and neck oncology at Dana-Farber Cancer Institute in Boston, Massachusetts, said the study was the "first official record of what we have all known."

5. At Dana-Farber, incoming patients' biopsy readings are reviewed by their own pathologists because 3-5% of diagnoses are changed.

6. The medical director at Dana-Farber disagrees that all biopsy results warrant a second pathology opinion. "Can it be done in a way to maximize the return? The most standard tumors, such as invasive breast cancer, don't need to be reviewed again. I don't want the public to panic about all pathology reviews."

CONCLUSIONS & RECOMMENDATIONS

- Conclusions

Based on the findings in this report, the following conclusions are provided:

1. Quality of care or the quality of the opinion issued for the samples analyzed was the most important single issue identified by the dermatologists. They identified accuracy of the opinion issued as being of critical importance.

   The accuracy of the opinion issued by a clinical laboratory can be a life or death matter as documented by public testimony at the committee's hearing on November 3, 1999. Also, the Boston Globe article dated December 1, 1999, cited research which documented the need for a second opinion in many instances to ensure the accuracy of the first opinion. This John Hopkins Medical Institutions study found 1.4% of biopsy analyses resulted in an inaccurate diagnosis. Therefore, the accuracy of the analysis must be ensured and potential health hazards must be detected at the earliest point in time.

2. The second issue of primary importance to the dermatologists was the ability to either select the clinical laboratory, or as an alternative, to be able to select the clinical laboratory to issue a second opinion when there was documented concern as to the quality of the first opinion.

3. The dermatologists also identified that the turnaround time on tissue samples from laboratories was an important concern. It appears that the turnaround time on tissue samples sent to clinical laboratories of their choice was considerably faster than from the laboratories managed care required them to use. However, it should be pointed out that a number of HMOs responded that if the dermatologists requested a faster turnaround time, the clinical laboratory they were required to use would comply.

4. Of the responding dermatologists, 69% reported incorrect diagnosis accuracy and 58% reported lost tissue samples. However, only 2% reported filing a complaint with the Agency for Health Care Administration, the agency that issues licenses to the clinical laboratories.

   Of the HMOs responding to the committee, 100% stated that they had no knowledge of lost or incorrect diagnoses. However, in their response to a questionnaire sent to all HMOs by the Agency for Health Care Administration, United Healthcare of Florida, Inc., stated that they had knowledge of complaints filed relative to misdiagnoses of tissue samples. In addition, one HMO that responded to the agency, but not to the committee, stated that they had knowledge

of complaints filed relative to misdiagnoses of tissue samples (Prudential Health Care Plan).

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A review of the statutes relating to clinical laboratories does not provide for a specific process or procedure for filing complaints about the quality of analyses the same as is provided in ch. 455, Florida Statutes, for physicians and other medical professionals.

5. Of the responding dermatologists, 98% would prefer that tissue samples be analyzed by a dermatopathologist rather than a general pathologist. However, a number of dermatologists responded that they know pathologists who are as knowledgeable and qualified as a dermatopathologist and issued opinions that were of equal quality.

   The knowledge and qualifications of the pathologist that issues the opinion was the primary reason given by the dermatologists for wanting to select which clinical laboratory should analyze tissue samples.

6. Due to the need for accurate diagnoses in life and death cases and the complexity of the diagnostic analysis, it would appear reasonable that such samples be handled differently from other clinical laboratory samples.

- Recommendations

There are approximately three options that are available to address the need to ensure the diagnostic accuracy and quality of clinical laboratories selected:

A. Change the law to require HMOs to select a group of several clinical laboratories from which dermatologists can then select their preferred provider of laboratory services;

B. Change the law to allow dermatologists to select the clinical laboratories to be used based on qualifications and their professional judgement; or

C. Continue to allow HMOs to select the clinical laboratory(s) for a dermatologist to use, but authorize the dermatologist to obtain second opinions from a laboratory of their choice when they provide documentation to justify the need for a second opinion.

Based on the findings and conclusions in this report, the following recommendations are provided:

1. Allow the HMOs to continue to provide a group of authorized clinical laboratories from which a dermatologist may choose; however, grant the dermatologist the authority to obtain a second opinion from a laboratory of their choice when they provide documentation to the HMO which justifies the need for a second opinion.

2. A specific procedure should be provided either by rule of the agency or by statute to address complaints against clinical laboratories. Such procedure should:

   (a) require the dermatologist or other physicians to notify the HMO of all questionable analyses or lost samples; and

   (b) require the HMO to maintain a record of all complaints and report such complaints to the Agency for Health Care Administration.

APPENDICES

COMMITTEE QUESTIONNAIRE

of

HEALTH MAINTENANCE ORGANIZATIONS

	Response
Av Med, Inc.	Yes
Aetna U.S. Healthcare, Inc.	No
AHL Select HMO, Inc.	No
American Medical Healthcare, Inc.	No
Amerihealth of Florida, Inc.	Yes
Beacon Health Plans, Inc.	Yes
Capital Group Health Services of Florida, Inc.	No
Cigna Health Care of Florida, Inc.	No
Community Health Care Systems, Inc.	No
Florida Health Care Plan, Inc.	No
Foundation Health, A Florida Health Plan, Inc.	No
Health First Health Plans, Inc.	Yes
Health Options, Inc.	Yes
Healthy Palm Beaches, Inc.	No
HIP Health Plan of Florida, Inc.	No
Healthplan Southeast, Inc.	No
Humana Medical Plan Inc.	No
Mayo Health Plans Inc.	No
Neighborhood Health Partnership, Inc.	No
One Health Plan of Florida, Inc.	No
Physicians Healthcare Plans, Inc.	Yes
Preferred Choice, The HMO of Florida Health Choice, Inc.	No
Preferred Medical Plan, Inc.	No
Prudential Health Care Plan, Inc. (Part of Aetna US Healthcare)	No
Healthease - Tampa General Healthplan	Yes
Sunstar Health Plan, Inc.	No
Vantage Health Plans, Inc.	No
Well Care HMO, Inc.	No
The Public Health Trust of Dade County	Yes
Total Health Choice, Inc.	No
United Healthcare of Florida, Inc.	Yes

STATE OF FLORIDA

AHCA

AGENCY FOR HEALTH CARE ADMINISTRATION

JEB BUSH, GOVERNOR

RUBEN J. KING-SHAW, JR., DIRECTOR

October 27, 1999

Representative Mike Fasano
Chair, House Health Care Licensing
& Regulation Committee
Room 1101, The Capitol
Tallahassee, FL 32399-1300

Dear Representative Fasano:

The Agency for Health Care Administration has completed your data collection request related to the use of clinical laboratories for anatomical pathological testing. Our staff polled all the commercially-licensed health maintenance organizations and compiled the results in the enclosed table.

If you need additional information please do not hesitate to call Sandy Berger in the Commercial Compliance Unit at 921-0100.

Sincerely,

Ann-Marie Brattain
Commercial Compliance Unit Manager

AMB/sb

Enclosure

cc: Bob Coggins, Legislative Analyst

HOUSE HEALTH CARE LICENSING REGULATION COMMITTEE
DERMATOPATHOLOGIST SURVEY

	NAME	DIRECT CONTRACT W/DERMATOPATHOLOGIST	CLINICAL LABS CONTRACT W/DERMATOPATHOLOGIST	COMPLAINTS/ GRIEVANCES MISDIAGNOSES OF SKIN DISEASE
1	Aetna US Healthcare, Inc.	NO	Yes/7	NONE
2	AHL Select HMO, Inc.	YES/1/Negotiating 6 more	None	NONE
3	Alpha Health Plan	NO	YES/3/LabCorp	NONE
4	American Medical Healthcare, Inc.			
5	AmeriHealth (formerly Anthem)	NO	YES/1/Consolidated Labs	NONE
6	Av-Med, Inc. & St. Augustine	NO	YES	NONE
7	Beacon Health Plans, Inc.	NO	YES/Quest Diagnostics	NONE
8	Capital Group Health Services of Florida, Inc.	YES/1	NO	NONE
9	CIGNA Health Care of Florida, Inc.	NO	None w/SmithKline	NONE
10	Community Health Care Systems, Inc.			
11	Florida 1st Health Plan, Inc.	YES/1	NO	NONE
12	Florida Health Care Plan, Inc.	NO	YES	NONE
13	Florida Health Choice dba Preferred Choice/MedChoice			
14	Foundation Health, A Florida Health Plan, Inc.	NO	YES/AmeriPath/50	NONE
15	Health First Health Plans, Inc.	NO	YES/1/Space Coast Path.	NONE
16	Health Options, Inc. & Health Options Connect	NO	Yes/20	NONE
17	HealthPlan Southeast, Inc.d.b.a. Discovery	Yes/1	YES/14	NONE
18	Healthy Palm Beaches, Inc. d.b.a. Personal Health Plan	NO	YES/2	NONE
19	HIP Health Plan of Florida, Inc.	NO	YES/2/Quest Diagnostics	NONE
20	Humana Medical Plan, Inc. & PCA Family Health Plan	NO	YES/5	PENDING QUERY
21	Mayo Health Plans, Inc.	NO	YES/3/St. Luke's/LabCorp	NONE
22	Neighborhood Health Partnership, Inc.			
23	One Health Plan of Florida, Inc.	NO	YES/14/AmeriPath	NONE
24	Physicians Healthcare Plans, Inc.			
25	Preferred Medical Plan, Inc.	YES/2	YES/5	NONE
26	Prudential Health Care Plan (Aetna purchased 8/13/99)	YES/14	YES	YES/7
27	Public Health Trust of Dade County dba JMH Health Plan	NO	YES/3/U of M	NONE
28	Sunstar Health Plan, Inc.	NO	YES/10-15	NONE
29	Tampa General Healthplan, Inc. d.b.a. Healthease	NO	YES/AmeriPath	NONE
30	Total Health Choice, Inc.	NO	YES/2/Quest Diagnostics	NONE
31	United Healthcare of Florida, Inc.	NO	YES/13/S.Fla Path & Ameripath	YES/2
32	Well Care HMO, Inc. d.b.a. Staywell Health Plan	NO	YES/SmithKline	NONE

STATE OF FLORIDA

AHCA

AGENCY FOR HEALTH CARE ADMINISTRATION

JEB BUSH, GOVERNOR

RUBEN J. KING-SHAW, JR., DIRECTOR

November 2, 1999

Bob Coggins
Legislative Analyst
House Health Care Licensing Regulation Committee
Room 1101, The Capitol
Tallahassee, FL 32399-1300

Dear Mr. Coggins:

The following shows the differences in the Department of Insurance's financial list and the Agency for Health Care Administration's list showing dermapathologists information.

Not on list or combined with new owner on Agency list:

Health Care USA, Inc. – CLOSED
Oxford Health Plans (FL), Inc. – CLOSED
Principal Health Care of Florida – Purchased by Health Options, Renamed Health Options Connect
St. Augustine Health Care, Inc. – Purchased by AvMed

On the Agency list but not on the DOI list:

Alpha Health Plan – is not a commercially licensed HMO (does not have a certificate of authority from the Department of Insurance but does have a health care provider certificate from the Agency and a contract to provide Medicaid services).

If you have further questions, please give me a call at 414-8979.

Sincerely,

Sandy Berger

Sandy Berger
Medical/Health Care Program Analyst

Post-it® Fax Note	7671	Date 11/2/99	# of pages ▶ 1
To Bob Coggins		From Sandy Berger	
Co./Dept.		Co.	
Phone #		Phone #	
Fax # 8-9933		Fax #	

Florida House of Representatives

John Thrasher, Speaker

HEALTH CARE LICENSING & REGULATION

HEALTH & FAMILY SERVICES COUNCIL

Mike Fasano
Chair

Everett Kelly
Vice Chair

MEMORANDUM

TO: Florida Licensed Dermatologists

FROM: Representative Mike Fasano MF(W)

DATE: August 2, 1999

SUBJECT: Questionnaire on dermatology/clinical lab related issues

****

Speaker Thrasher has approved an interim project regarding the relationship between dermatologists, managed care providers, and clinical laboratories. Your assistance is necessary if the Legislature is to make an informed decision relating to this issue and to develop possible legislative changes, if necessary.

Enclosed is a short questionnaire to obtain information on dermatological services and the clinical laboratories that assist dermatologists in making their patients' diagnoses. **It is imperative that you complete the questionnaire and return it in the stamped, self-addressed envelope no later than August 11, 1999.**

If additional space is needed for comments, please use an attachment. Your prompt assistance is greatly appreciated.

MF/bc/th

Enclosure

Lucretia Shaw Collins, Staff Director
1101 The Capitol Tallahassee, Florida 32399-1300 (850) 487-3771 FAX (850) 488-9933

QUESTIONNAIRE/SURVEY - DERMATOLOGISTS

1. Do you participate in managed care?
   NO_____If **no**, why not? **YES**_____If **yes**, to what extent?

2. If you participate in managed care, are you required to utilize specific pathology labs?
   NO_____ **YES**_____

3. Would you participate more in managed care if you were not restricted in your choice of pathology labs?
   NO_____ **YES**_____

4. **PLEASE SELECT ONE:**

   a. I am required to use specific labs for managed care patients_____
   b. I select the laboratory(s) for <u>all</u> patients seen in our office_____

5. Which laboratories do managed care companies most frequently require you to use?

6. Has a laboratory ever lost a specimen?
   NO_____ **YES**_____If **yes**, which lab(s) and how many?

   Have you filed a complaint with the Agency for Health Care Administration?
   NO_____ **YES**_____

7. Has a laboratory ever provided you with an incorrect diagnosis?
   NO_____ **YES**_____If **yes**, which lab(s) and how many?

   Have you filed a complaint with the Agency for Health Care Administration?
   NO_____ **YES**_____

8. What is the average turn around time on specimens for
your choice of lab(s)_____
required managed care lab(s)_____

9. If you question the laboratory findings, do you obtain a second opinion from a different laboratory?
NO_____ **YES**_____

10. If required to use a specific laboratory by managed care, are you allowed to obtain a second opinion from a laboratory of your choice?
NO_____ **YES**_____

11. Have you been involved in any lawsuits that resulted from the quality of a laboratory's work?
NO_____ **YES**_____**If yes**, how many?_____

12. Do you prefer that your biopsies be read by a dermatopathologist rather than a general pathologist?
NO_____ **YES**_____

13. Do you believe a dermatologist should be allowed to select the most qualified laboratory in their professional opinion?
NO_____ **YES**_____

14. As an alternative, would the ability to get 2nd opinions from your choice of labs be helpful?
YES_____ **NO**_____If **no**, why not?

Please provide name, title, address, and telephone number of individual completing this survey.

Florida House of Representatives

John Thrasher, Speaker

HEALTH CARE LICENSING & REGULATION

HEALTH & FAMILY SERVICES COUNCIL

Mike Fasano
Chair

Everett Kelly
Vice Chair

October 11, 1999

M E M O R A N D U M

TO: Health Maintenance Organizations

FROM: The Honorable Mike Fasano, Chairman
Health Care Licensing & Regulation Committee

RE: Anatomical Pathology

****

A number of dermatologists and other individuals have expressed concerns about the accuracy of the tissue analyses (anatomical pathology) received from the various laboratories which they are required to use.

As a result of these concerns, our committee is reviewing the requirement that dermatologists who contract with managed care organizations send their tissue specimen to a particular laboratory for analysis and to determine the accuracy of the results of said analysis.

As part of this review, the committee surveyed all members of the Florida Society of Dermatologists and the Florida Society of Dermatologic Surgeons. Of the 444 questionnaires mailed out, the committee received a response from 259 or 58.3 %. A response rate of 58.3% is considered acceptable for drawing statistically valid conclusions.

Based on the 259 responses received, the great majority were required to use either one or all three of the following laboratories for their tissue samples: SmithKline Beecham Clinical Laboratories; Laboratory Corporation of America; or Quest Diagnostics Laboratories.

It would be helpful if your organization would respond to the attached list of questions and return no later than October 18, 1999. If you have any questions please contact Robert Coggins at 850/487-3771.

MF/RC/th

Attachment

Lucretia Shaw Collins, Staff Director
1101 The Capitol Tallahassee, Florida 32399-1300 (850) 487-3771 FAX (850) 488-9933

INFORMATION REQUEST

1. Do you require your dermatologists to use one of the following three laboratories: SmithKline Beecham Clinical Laboratories; Laboratory Corporation of America; or Quest Diagnostics Laboratories?

   ____Yes ____No

2. Nearly 58% of the dermatologists that responded to the questionnaire identified one or more examples of lost samples and 69% identified examples of one or more incorrect diagnoses. Do you have knowledge of such cases?

   ____Yes ____No If yes, how did you resolve such cases?

3. A majority of the dermatologists that responded identified that the turn around time on diagnoses of tissue samples from laboratories of their choice was considerable faster than from the laboratories managed care required them to use. For instance, 72% received responses in three days or less from laboratories of their choice, while 90.5% received responses in 14 days or less from laboratories managed care required them to use. A majority (56.7%) stated it took 10 days or less to receive a response. Is a 10 to 14 day response time from the laboratories that dermatologists are required to use an acceptable time period?

   ____Yes ____No If no, please provide any recommendations on how to shorten the time period.

4. It has been suggested that tissue samples are a very small percentage of all analyses performed by clinical laboratories. What percentage of all analyses performed by contracted laboratories are tissue samples?

   Number_____ (as a percent) Dollar amount_____ (as a percent)

5. Would your organization consider removing anatomical pathology in its entirety from capitated laboratory contracts?

   ____Yes ____No

6. As an alternative to #5, would your organization consider allowing a dermatologist to select a laboratory if the contracted laboratory does not meet the same standards as the laboratory selected by the dermatologist?

   ____Yes ____No

7. Do you have any alternative recommendations or suggestions to improve the timely response and quality of the results of tissue analyses?

   ____Yes ____ No If yes, please provide them.

Please provide the name of the HMO and the name, title, address, and telephone number of the person completing this survey.

Biopsies need 2d review, researchers say

By Karen Hsu, Globe Correspondent, 12/01/99

Patients have long been told to seek a second opinion from an examining doctor, but they also should ask for a second review on laboratory readings by pathologists to prevent the wrong treatment, researchers say.

In a study of 6,171 cancer patients referred to Johns Hopkins Medical Institutions in Baltimore, researchers found 86 patients, or 1.4 percent, who initially had a "totally wrong" diagnosis after a biopsy result, said Dr. Jonathan Epstein, professor of pathology, urology, and oncology at Johns Hopkins.

If the reading is wrong, "you can go to the best clinician, but have the wrong treatment," said Epstein, an author of a report on the study in the current issue of Cancer.

One patient was supposed to have his middle ear removed because the first diagnosis was cancer of the ear canal. But the second pathology report at Hopkins found the patient to have a fungal infection that could respond to medicine.

The review at Hopkins revealed false positives, conditions misdiagnosed as cancer. False negatives are cancerous tissues that are misidentified as noncancerous.

Epstein and his colleagues compared the original pathologists' reports that patients brought to Hopkins with the reports done by Hopkins pathologists on the same patients. In 23 percent of the suspect cases, patients' diagnoses changed from "decidedly" malignant to benign, Epstein said. Past studies of this problem have focused on a specific cancer, but this study looked at all types of cancer.

Dr. Marshall Posner, medical director of head and neck oncology at Dana-Farber Cancer Institute in Boston, said the study by Epstein and his colleagues was the "first official record of what we have all known."

Mistakes could not be predicted by the size of the hospital or the level of experience of its physicians, Epstein said. Some mistakes came from community hospitals, and others from teaching hospitals, he said.

Between January 1995 and December 1997, two pathologists at Sturdy Memorial Hospital in Attleboro allegedly misread 20 biopsies on 19 patients with prostate cancer, saying they were free of cancer. Sturdy discovered the errors after a urologist found that one of his patients had been misdiagnosed. The hospital now has biopsies reviewed by two pathologists, instead of one.

Because of situations like Sturdy's, Epstein recommends institutions set up policies

requiring a review of the original biopsies before patients undergo surgery or other major therapy. Patients can also ask their clinicians to send their biopsies to another pathologist for review.

Epstein, who reviews 4,500 prostate cases annually from other pathologists, said the rate of false negatives at Sturdy was higher than he would have expected, but he noted that prostate cancer is one of the hardest to diagnose.

At Dana-Farber, incoming patients' biopsy readings are reviewed by Dana-Farber's own pathologists because 3 percent to 5 percent of diagnoses are changed, said Posner.

But Posner disagrees that all biopsy results warrant a second pathology opinion. "Can it be done in a way to maximize the return? The most standard tumors, such as invasive breast cancer, don't need to be reviewed again. I don't want the public to panic about all pathology reviews."

This story ran on page A09 of the Boston Globe on 12/01/99.

		1st Quarter	2nd Quarter
	Annual 1998	1999	1999
		INCOME OR	INCOME OR
HMO DATABASE INFORMATION	INCOME OR	(LOSS)	(LOSS)
FOR THE YEAR ENDED	(LOSS)		
1998 and 1st and 2nd Quarters 1999			
Aetna US Healthcare	(16,231,051)	-7,983,289	-3,826,657
AHL Select HMO, Inc.	(82,854)	75,902	67,560
American Medical Healthcare	(2,494,674)	-220,351	-109,443
AmeriHealth of Florida,Inc.	(7,789,485)	-5,167,382	-4,605,121
AvMed, Inc.	(25,513,356)	-6,081,924	-4,104,600
Beacon Health Plans, Inc. (9/30/98)	(6,991,783)	81,707	-60,467
Capital Group Health Services of Florida	(7,471,753)	340,649	924,410
CIGNA Healthcare of Florida, Inc.	18,853,792	7,698,007	2,699,890
Community Health Care Systems, Inc.	(6,631,091)	-923,067	-1,681,554
Florida 1ST Health Plan, Inc. (9/30/98)	(3,042,037)	-365,056	-215,106
Florida Healthcare Plan, Inc. (6/30/98)	(1,118,738)	107,519	-544,286
Foundation Health, A Florida Health Plan, Inc. (6/30/98)	1,257,307	-3,240,042	-3,492,055
Health Care USA, Inc.	167,334	603,745	2,415,547
Health First Health Plans, Inc.	(1,800,785)	872,257	700,533
* Health Options, Inc. Health Options Gomeat	(14,232,418)	12,100,342	-5,724,680
Healthplan Southeast, Inc.	(10,030,916)	-2,264,270	-6,799,148
Healthy Palm Beaches, Inc. (9/30/98)	118,386	463,407	-124,122
HIP Healthplan of Florida, Inc.	87,517	10,078	-38,693
Humana Medical Plan, Inc.	137,697,543	-1,095,128	-7,165,853
Mayo Health Plan, Inc.	(2,299,939)	18,958,100	4,081,297
Neighborhood Health Partnership, Inc. (6/30/98)	5,137,378	-168,411	-263,707
One Health Plan of Florida, Inc.	210,882	1,644,953	1,635,542
* Oxford Health Plans (FL), Inc. closed doors	(5,547,761)	112,825	-100,058
Physicians Healthcare Plan, Inc.	4,472,074	557,468	-292,844
Preferred Choice, the HMO of FL, Health Choice, Inc.	(2,370,619)	1,569,470	2,587,688
Preferred Medical Plan,Inc.	1,457,845	1,188,451	-270,553
Principal Health Care of Florida, Inc.	4,541,290	360,598	259,982
* Prudential Health Care Plan, Inc. (Florida Divisions) Aetna	(41,552,827)	-51,991,229	-10,829,178
Public Health Trust of Dade County, The (6/30/98)	77,773	-732,368	-1,049,831
* St. Augustine Health Care, Inc. AvMed	(5,794,098)	-177,600	-516,815
SunStar Health Plan, Inc.	(654,247)	520,768	1,053,477
Tampa General Healthplan (9/30/98)	(1,244,290)	96,322	-84,530
Total Health Choice, Inc.	(5,897,792)	-190,724	-321,261
United Healthcare of Florida, Inc.	(35,285,501)	3,218,951	-1,984,695
Weil Care HMO, Inc.	2,360,488	1,624,527	1,081,155
TOTALS	(27,638,406)	-28,374,776	-35,161,362
** The notes found on the final page of this document are an integral part of this report. All information on this report was obtained from the annual financial statements filed with the Department of Insurance.			

* Bought out or closed doors in Florida

Skin cancer suit spotlights fight over HMO labs

By Sanjay Bhatt
Palm Beach Post Staff Writer

WEST PALM BEACH — Martie Wrock-Ryland's smile is as wide as the scar left on her back by "the Beast."


Wrock-Ryland

It's been two years since a surgeon removed cancerous tissue from the pale skin above her right shoulder blade. But the surgeon didn't kill what Wrock-Ryland calls the Beast. It ducked into her lymph system and forced her to undergo two more surgeries that have smashed her body's defenses — though not her spirit.

She blames her HMO and the lab and doctors who didn't detect the cancer at first, according to a suit filed last week in Palm Beach Circuit Court. The 52-year-old Boynton Beach woman has less than a 50 percent

Please see **SKIN CANCER, 14A**

SKIN CANCER
From 1A

chance of surviving the next five years, the suit said.

"This is an area of public concern because if you miss it, it's a death sentence," said Wrock-Ryland's West Palm Beach lawyer, Gregory Barnhart. "This is a slow, agonizing, unjust and entirely preventable death."

The case raises issues at the heart of a long simmering national debate between health maintenance organizations and doctors. The two sides are locked in a tug-of-war over who controls where life-and-death decisions concerning cancer are made.

Wrock-Ryland is suing SmithKline Beecham Clinical Laboratories, Dr. John Karroum of Miramar and Dr. John Kulick of Boca Raton. She says in her complaint that they were negligent in failing to detect the cancer in August 1996.

'Don't want to be a victim'

She also is suing her HMO, Humana Medical Plan Inc., which contracted with the three other defendants.

"I don't want to be a victim," Wrock-Ryland said. "I want to help other people fight melanoma. I want to see a cure for melanoma. . . . (And) I want to see accountability."

The Florida Society of Dermatology in Tallahassee said that managed-care companies could be endangering patients' lives by not hiring doctors who specialize in skin disease to analyze all skin specimens.

"We've tried convincing the managed-care companies to behave more responsibly and use the most qualified lab," said Dr. Steven Rosenberg, a West Palm Beach dermatologist now treating Wrock-Ryland.

Rosenberg is no fan of managed care: He left an HMO five years ago, and two years ago he led a successful fight to give

> *'If physicians are going to have reservations about the accuracy of a lab, then it should be sent to a lab where they would be more comfortable about quality in the first place.'*
>
> **DR. STEVEN ROSENBERG**
> Dermatologist

HMO patients in Florida direct access to dermatologists.

"We need to develop some legislation (to enable) the physician to select the most appropriate lab for the patient rather than the insurance company, which may be looking to other concerns," Rosenberg said.

The American Medical Association passed a resolution in June supporting the right of patients in HMOs to choose where to send a tissue specimen.

The Florida House committee on health-care licensing and regulation will examine the issue in the 2000 session, the committee's chairman, Rep. Mike Fasano, R-New Port Richey, said in a letter to Rosenberg.

But it'd be too late to help Wrock-Ryland. The black growth on Wrock-Ryland's nape didn't alarm her when she first visited Kulick in August 1996 at a Humana office in Boynton Beach. "I've been a sun worshipper so I know to get these things taken off," she said. The mole was about as big as a pencil eraser.

According to the complaint, Kulick took a tissue sample and sent it to SmithKline, where Karroum diagnosed it as basal cell carcinoma, a skin malignancy that rarely spreads but requires removal.

Based on Karroum's diagnosis, Kulick told Wrock-Ryland she didn't need any more treatment and didn't remove the rest of the

growth, the complaint said.

Neither Karroum nor Kulick returned calls for this story.

Wrock-Ryland returned to see Kulick five months later because she found another growth on her back. This time, SmithKline's pathologist said it was malignant melanoma.

"I knew it was very deadly," Wrock-Ryland recalled. "I went over to a neighbor's house and cried."

In May, a University of Miami pathologist specializing in skin disease analyzed the first biopsy and found it to be malignant melanoma, the lawsuit said.

Who's performing biopsies?

A spokesman for SmithKline Beecham said in a statement that the company's pathologists are all board certified and are "qualified to review tissue biopsies of all types."

SmithKline performs more than 750,000 biopsies a year. The company said it does not always have doctors with specialty in dermatology review skin biopsies, just as not all breast biopsies are read by doctors specializing in breast disease.

"It is not a standard of practice," the company said.

Nevertheless, the suit identified Karroum as a pathologist specializing in skin disease.

Dr. Ronald Harris, a pathologist specializing in dermatology at the University of Utah, agrees with the company. "For the most part, there's been a fairly good job done (by general pathologists) on those biopsies."

The nation's leading trade association of pathologists, the College of American Pathologists, said the problem is not a lack of pathologists specializing in skin disease. Rather, it's the physical and psychological distance between doctors and huge clinical laboratories with exclusive contracts.

"(Managed-care companies) get a lower price but communication between the doctor and pathologist is not as good," said Dr. Gordon Johnson, a St. Louis pathologist and member of the college. Doctors treating patients enrolled in an HMO are required to use the HMO's laboratory for all tests. Humana spokesman Tom Noland said the insurer no longer contracts with SmithKline for laboratory services. Since January 1998, LabCorp., another national giant, has served Humana's HMO members, he said.

Noland also said the insurer pays for second opinions on biopsies if doctors request it. "It's typical for us to accede to the physician's desire and to support it and to pay," Noland said.

Rosenberg, who has avoided accepting HMO patients, said that second opinions aren't encouraged by HMOs.

"If physicians are going to have reservations about the accuracy of a lab, then it should be sent to a lab where they would be more comfortable about quality in the first place," he said.

Meanwhile, Wrock-Ryland has thrown herself at her disease: She's joined support groups on the Internet, signed up for a clinical trial and refused to let the Beast ruin her sunny disposition.

"I choose not to look at the statistics because I don't like 'em," she said. "I've got a 91-year-old mom to take care of, a 13-year-old son and a business. I want to live."

Skin cancer on the rise

FLORIDA

Year	New cases	Deaths
1990	1,900	450
1995	2,300	490
1999	3,000	n/a

UNITED STATES

Year	New cases	Deaths
1990	27,600	6,300
1995	34,100	7,200
1999	44,200*	7,300*

*Estimated; n/a: Not available

Source: American Cancer Society

HEATHER KONG/Staff Artist